

EXHIBIT 33

From: Harper, Karen
To: Santowski, Michael J
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Subject: Suspicious Order Monitoring Presentation for EC
Attachments: Training for Executive Committee 04_2011.ppt

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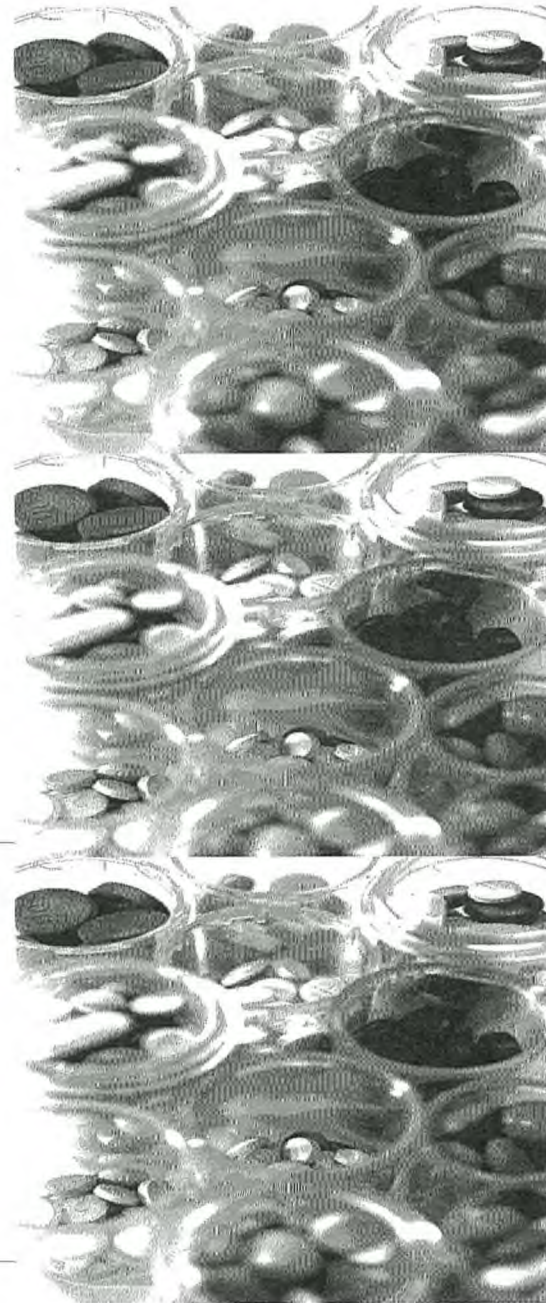
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Mallinckrodt Controlled Substance Suspicious Order Monitoring Program

Presentation for
Executive Committee
April 25, 2011



Suspicious Order Monitoring Presentation Agenda

- Suspicious Order Monitoring Team Composition
- Regulatory Background
- By the Numbers
- Oxycodone Market Analysis
- Florida Distribution Trends
- DEA Past Communication and Distributor Initiative
- Previous Suspicious Order Monitoring Program
- Recent Industry Enforcement Action and DEA Guidance
- Suspicious Order Monitoring Enhancements
- OxyContin Express Video
- Florida Pain Clinic Raids
- Suspicious Order Monitoring Next Steps
- DEA and Distributor Feedback



Mallinckrodt Suspicious Order Monitoring (SOM) Team Composition

Leadership Team

Meets once per month

Controlled Substance Compliance
Security
Legal

Steering Committee

Meets once per quarter

Controlled Substance Compliance
Security
Legal
Commercial
Customer Service
Finance
Medical Affairs/REMs

Subcommittees

As needed



DEA Policy on Suspicious Orders

21 CFR 1301.74



- Requires registrants to design and operate a suspicious order identification system
- Requires that registrants report suspicious orders to DEA when discovered via monitoring process
- Registrant is reminded that their responsibility does not end merely with the filing of a suspicious order report
- DEA does not approve or otherwise endorse any specific program for reporting suspicious orders
- *Registrant must conduct an independent analysis of suspicious orders prior to completing a sale to determine whether the controlled substances are likely to be diverted*

By the Numbers



There are currently 1,363,883 DEA registrants
795 Distributor registrants
528 Manufacturing registrants

"DEA must rely on the States and individual registrants to monitor"



COVIDIEN

Covidien has 1,300+ controlled substance customer accounts

1,100+ Generics & Specialty Brands
200+ Active Pharmaceutical Ingredients

Oxycodone Market Analysis 04/12/11

Product Description	Oxy/APAP Tablets	Oxy/APAP Caps (5/500)	Oxy Tablets
MAL Share FY10Q4	40%	33%	52%
MAL Share FY11Q1	39%	31%	56%
Actavis		1%	25%
Amneal	5%		
Caraco			2%
Endo	15%		
Halsey		1%	
KVK-Tech			3%
Qualitest	5%	12%	12%
Roxane	3%	16%	
Teva		38%	
Watson	31%	1%	
Mylan	2%		
CorePharma			2%
TOTAL	100.0%	100.0%	100.0%

Florida Distribution of Oxycodone

98 of the top 100 doctors dispensing Oxycodone nationally are in Florida

By far, more oxycodone is dispensed in the state of Florida than in the remaining states combined

data per Florida Governor's Press Office 03/28/11

DEA reiterates responsibilities in light of the growing Rx drug abuse problem



**U.S. DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION**

www.dea.gov

Washington, D.C. 20537

MALLINCKRODT INC
3600 NORTH SECOND STREET
ST LOUIS MO, 63147-0000

December 27, 2007

|||

In reference to registration
PM0037451

Dear Registrant:

This letter is being sent to every entity in the United States registered with the Drug Enforcement Administration (DEA) to manufacture or distribute controlled substances. The purpose of this letter is to reiterate the responsibilities of controlled substance manufacturers and distributors to inform DEA of suspicious orders in accordance with 21 CFR 1301.74(b).

In addition to, and not in lieu of, the general requirement under 21 USC 823, that manufacturers and distributors maintain effective controls against diversion, DEA regulations require all manufacturers and distributors to report suspicious orders of controlled substances. Title 21 CFR 1301.74(b), specifically requires that a registrant "design and operate a system to disclose to the registrant suspicious orders of controlled substances." The regulation clearly indicates that it is the sole responsibility of the registrant to design and operate such a system. Accordingly, DEA does not approve or otherwise endorse any specific system for reporting suspicious orders. Past communications with DEA, whether implicit or explicit, that could be construed as approval of a particular system for reporting suspicious orders, should no longer be taken to mean that DEA approves a specific system.

The regulation also requires that the registrant inform the local DEA Division Office of suspicious orders when discovered by the registrant. Filing a monthly report of completed transactions (e.g., "excessive purchase report" or "high unit purchases") does not meet the regulatory requirement to report suspicious orders. Registrants are reminded that their responsibility does not end merely with the filing of a suspicious order report. Registrants must conduct an independent analysis of suspicious orders prior to completing a sale to determine whether the controlled substances are likely to be diverted from legitimate channels. Reporting an order as suspicious will not absolve the registrant of responsibility if the registrant knew, or should have known, that the controlled substances were being diverted.

The regulation specifically states that suspicious orders include orders of an unusual size, orders deviating substantially from a normal pattern, and orders of an unusual frequency. These criteria are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious. Likewise, a registrant need not wait for a "normal pattern" to develop over time before determining whether a particular order is suspicious. The size of an order alone, whether or not it deviates from a normal pattern, is enough to trigger the registrant's responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer, but also on the patterns of the registrant's customer base and the patterns throughout the relevant segment of the regulated industry.

Failure to maintain effective controls against diversion is inconsistent with the public interest and may result in the revocation of the registrant's DEA license

***DEA can immediately
suspend or revoke
registration for violations of
the Controlled Substances
Act and regulations.***

DEA Distributor Initiative, 2008

DEA suspends licenses of distributors for not maintaining effective controls against diversion of controlled substances

Amerisource Bergen

Orlando, FL Distribution Licenses suspended for four months

Cardinal

DEA license suspended at three distribution centers for ten months

Cardinal pays \$34 million due to enforcement actions

McKesson

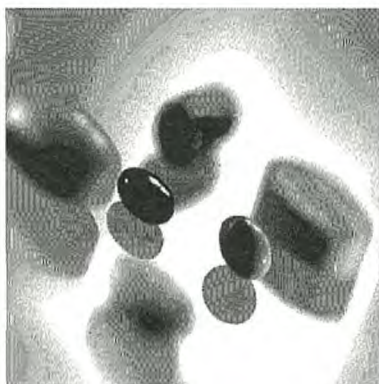
McKesson Corporation Agrees to Pay More than \$13 million to settle claims that it failed to report suspicious sales of prescription medications

Masters Pharmaceutical

Masters is a Mallinckrodt Distributor customer

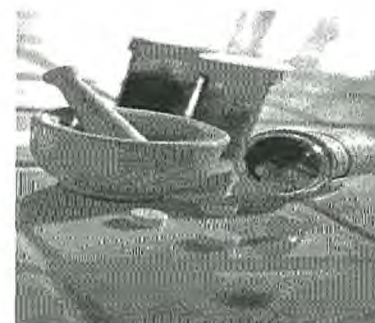
Masters sold more than 4 million doses of hydrocodone, phentermine and alprazolam to internet pharmacies between 2005-2008 without reporting the sales to the DEA

Although Masters reported suspicious orders during the 2005 and 2008 period in question, the DEA believed that some orders placed by 10 pharmacies **should have been reported** as suspicious



Fined \$500,000

CVS Fines



CVS Caremark's Latest Legal Headaches? A Record \$77.6 Million Settlement with DEA

Published October 15, 2010

The already extensive list of government entities scrutinizing CVS Caremark's behavior just got longer. DEA joins the alphabet soup with a record \$77.6 million settlement, which includes a \$75 million fine (the largest ever under the Controlled Substances Act) and the forfeiture of \$2.6 million in profits from illegal sales. Meanwhile, a California court upheld a \$42,000 fine against Caremark for acting in "bad faith" in a whistleblower lawsuit.

In a statement, the U.S. Drug Enforcement Administration said the company, *"admitted that it unlawfully sold pseudoephedrine [PSE] to criminals who made methamphetamine. As part of the agreement with federal prosecutors, CVS has agreed to pay \$75 million in civil penalties and to forfeit the \$2.6 million in profits the company earned as a result of the illegal conduct."*

Existing SOM Program (pre 06/10)



- Customer completes checklist prior to establishing new account and once annually thereafter
- Credit performs Dun & Bradstreet and other information checks (Associated Pharmacies)
- CDIG and CSRs follow existing procedure on verification of customer DEA registration, quota, DEA 222 Form
- Peculiar Order report flags direct orders of unusual size, frequency, incremental increases, purchase of a new molecule or business from a new customer
- Any Peculiar Order issues that are not resolved by internal investigation are referred to the Controlled Substance Compliance Group Security Director and DEA Compliance Manager for further investigation
- Security Director and DEA Compliance Manager consult with Commercial Group Business Manager regarding ship or no ship decision based on findings of their investigation
- Security Director and DEA Compliance Manager report orders that have been elevated from Peculiar to Suspicious to DEA

Industry Events 06/16/10



Harvard Drug (Mallinckrodt Distributor customer)
Livonia, Michigan

Controlled Substance License Suspended for Livonia location
Approval to resume shipping CIII-CV negotiated within one week
CII restriction shipments at Livonia still in force

Sunrise Distributors (Mallinckrodt Distributor customer)
Sunrise, Florida

License Suspended pending further investigation
License voluntarily surrendered

DEA St. Louis Conversation 07/20/10

Mallinckrodt was named as supplier of Harvard Drug Distributor at a DEA training session in Washington DC

Pain Clinic undercover operations reveal a “cattle call” scenario

Mallinckrodt is viewed as the kingpin within the drug cartel

DEA is implementing a “new direction” initiative aimed at manufacturers of Oxycodone

DEA expectation has evolved to require that manufacturers know their customers’ customers



SOM Program Enhancements Achieved

Monthly review of Chargeback Reports

Data analysis reveals

% of Oxycodone purchased per Distributor

% of Distributor Oxycodone sold to Florida

Pharmacies that purchase from multiple Distributors

Distributor Audit Program Implemented

Met with DEA Albany and DEA St. Louis to discuss Chargeback Report observations

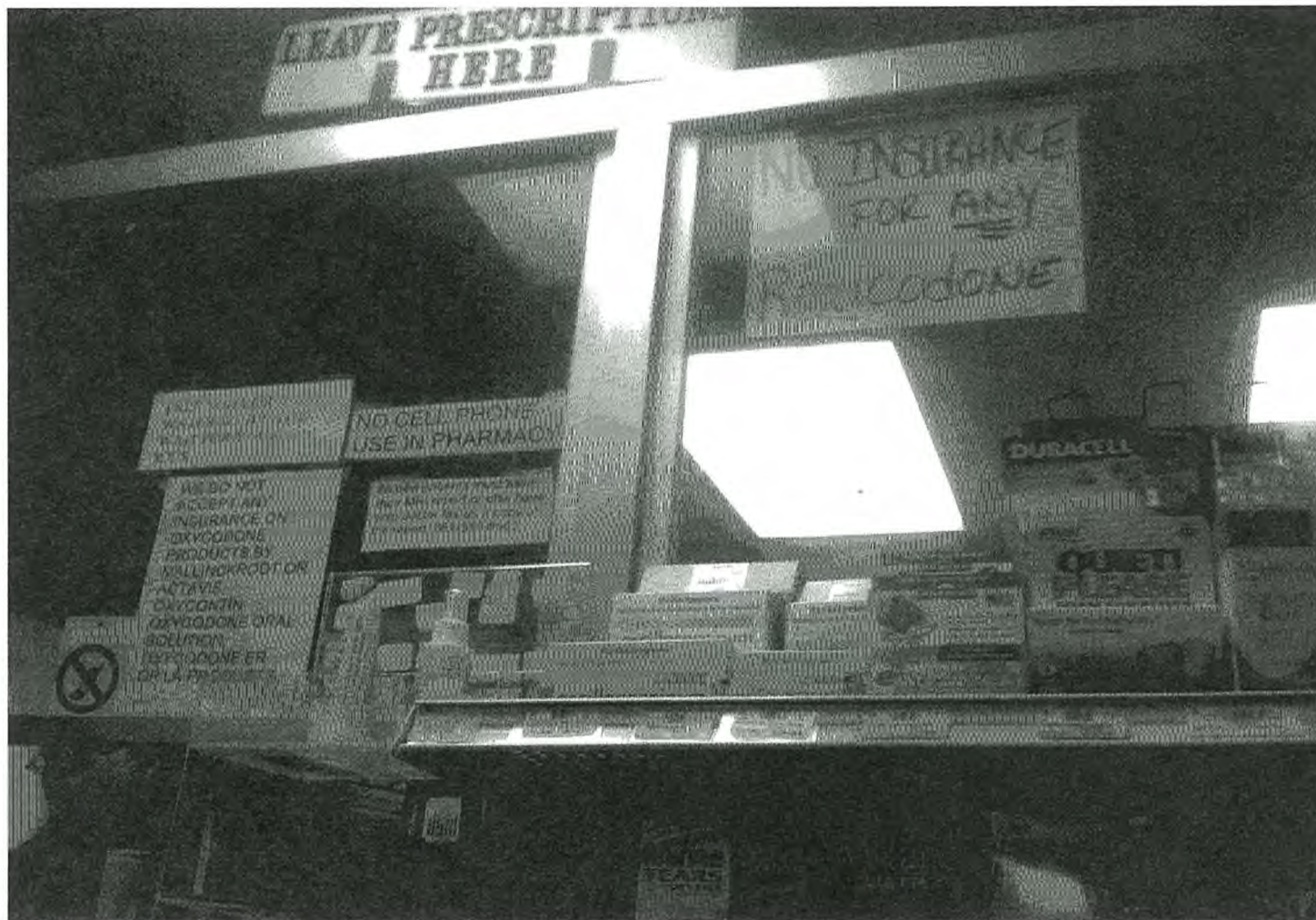
Conducted on-site SOM Audit of Keysource, Masters, Cedardale 12/10 and 01/11

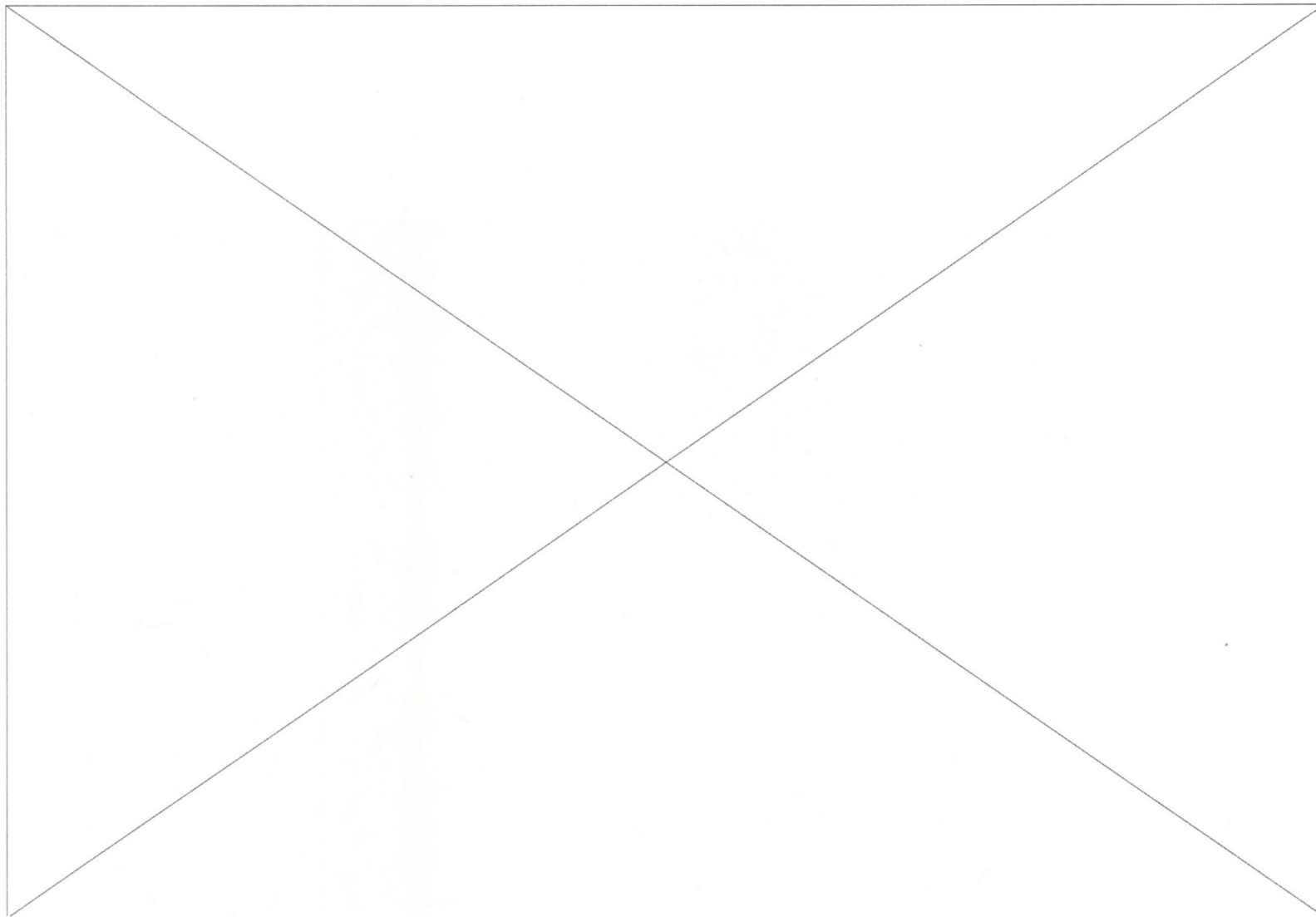
Informed Distributors of audit findings 02/11

All communication to Distributors has been pre-reviewed by Commercial

Checking law enforcement newsletters and DEA webpage for match with pharmacy indirect customers







DEA Florida Pain Clinic Raids

Florida Sun Sentinel

3:54 p.m. EST, February 23, 2011

Drug investigators raided an untold number of pain clinics from Miami to West Palm Beach on Wednesday, arresting doctors and clinic owners in the biggest single strike at Florida's pain pill industry.

Hundreds of officers from federal, state and local agencies fanned out in an orchestrated sweep that shut down some of the busiest and best known pain clinics in Broward, Palm Beach and Miami-Dade counties, said officials who spoke on the condition of anonymity.

In Delray Beach, police arrested Dr. Zvi Harry Perper, the son of Broward Medical Examiner Dr. Joshua Perper, at Delray Pain Management, 201 N. Swinton Ave. Zvi Perper is listed as the owner of the clinic, which is run by manager Kenneth Murry, who opened it in early 2009.

In Oakland Park, a half dozen medical personnel in scrubs were handcuffed and arrested at a high-volume clinic called Commercial Medical Group, 291 E. Commercial Blvd.

Arrests also were made at by agents raiding 45th Street Medical in Lake Worth, which is owned by Dr. Robert Ellessar, federal officials said. Agents raided many more locations, seizing records as part of ongoing investigations.

"We're so happy all this is happening," said Julie DePasquale, a clerk at German Bread Haus two doors from the Oakland Park clinic. She said it is popular with out-of-state pill seekers. "I'll feel safer coming to work at 7 o'clock in the morning. The druggies are out there like the night of the living dead, waiting for that place to open. It's scary."

The raids were led by agents from the U.S. Drug Enforcement Administration, the Broward Sheriff's Office, the Palm Beach County Sheriff's Office and police departments from the state and cities. Florida Department of Health inspectors were on hand to initiate disciplinary actions against clinic doctors and owners.

SOM Distributor Audit Next Steps

Work with Finance to synchronize In/Out Distributor Chargeback Audits

Revise Customer Checklists (sent by Customer Data Integrity/CDIG to all accounts)

Work with CDIG on policy matters

Will continue to communicate with Commercial Group



Feedback Received



Distributors

Positive feedback and full audit cooperation from Keysource, Masters, Cedardale

H.D. Smith, Amerisource Bergen, McKesson, Quest, and others volunteering for audits

DEA St. Louis

Agency looks to Mallinckrodt as the leader in industry to be the leader in SOM

Review of Company record keeping systems to incorporate into SOM is a great benefit

DEA Albany

Appreciated the visit by Mallinckrodt to explain SOM initiatives

DEA Washington DC

Granted 3,900 kg AA Oxycodone Quota for Hobart 12/13/10 (3,900 kg AA requested 10/14/10)

Will be training Manufacturing Registrants on DEA SOM expectations

DEA Industry Consultant

Mallinckrodt has taken a brave and bold step within industry to upgrade SOM program

Pharmacy 54 Empty Mallinckrodt Oxycodone Pill Bottles - eBay (item 280580022565 en... Page 1 of 6

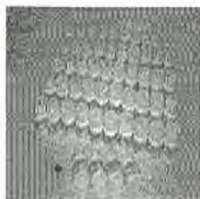


Listed in category: Crafts > Multi-Purpose Craft Supplies > Display & Storage

Item 280580

Pharmacy 54 Empty Mallinckrodt Oxycodone Pill Bottles

blask_fl (287 ★)



Item condition: Used

Time left: 3d 05h (Oct 31, 2010 17:05:17 PDT)

Bid history: 0 bids

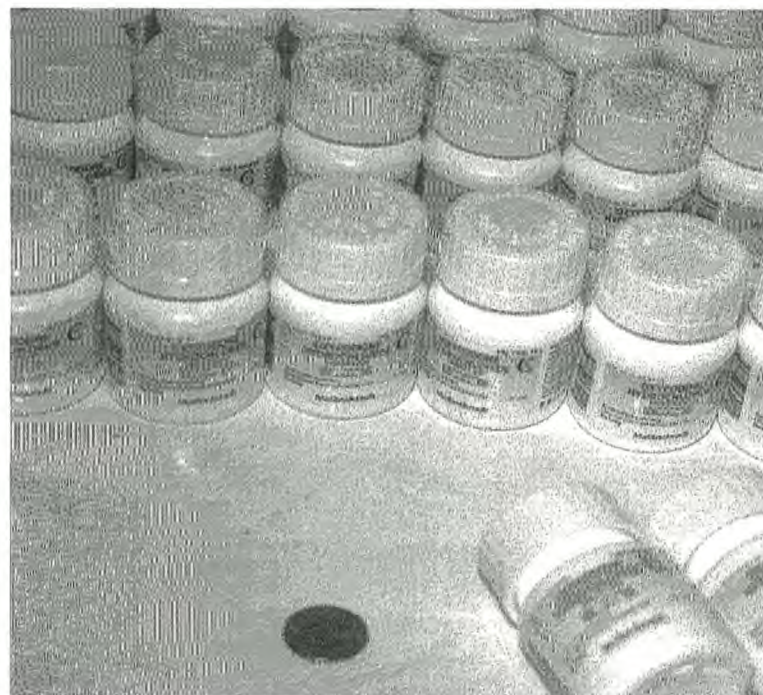
Starting bid: US \$0.99



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Pharmacy 54 Empty Mallinckrodt Oxycodone Pill Bottles - eBay (item 280580022565 en... Page 3 of 6



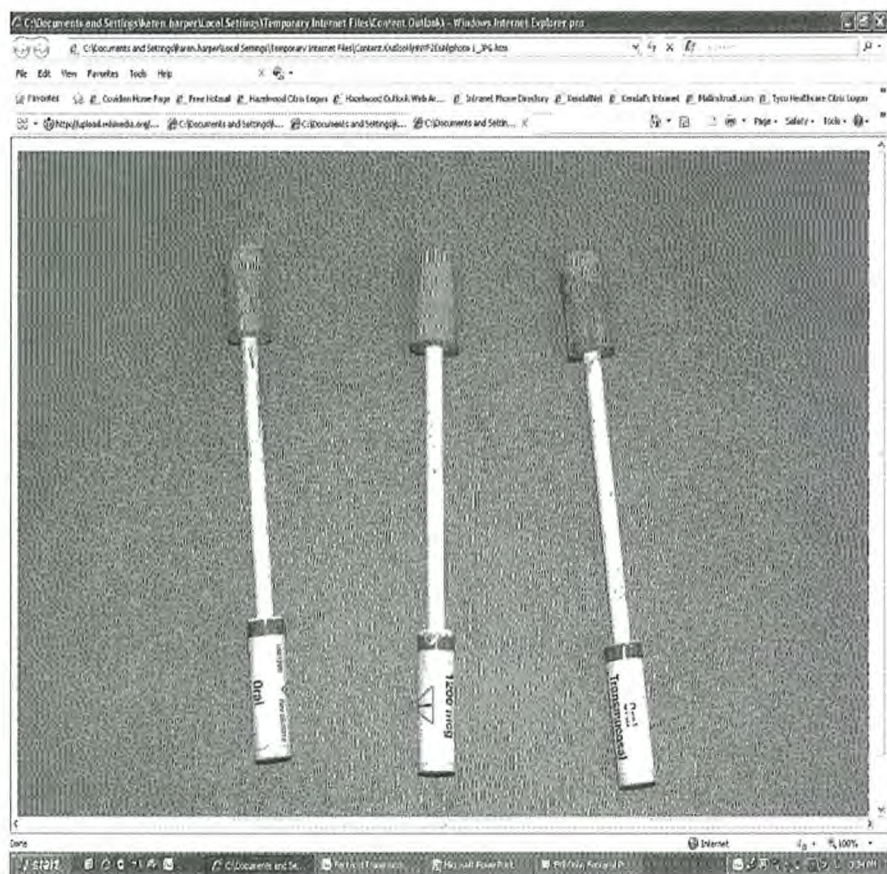
You are bidding on 54 cleaned used empty pill bottles with 54 child safety caps/lids.

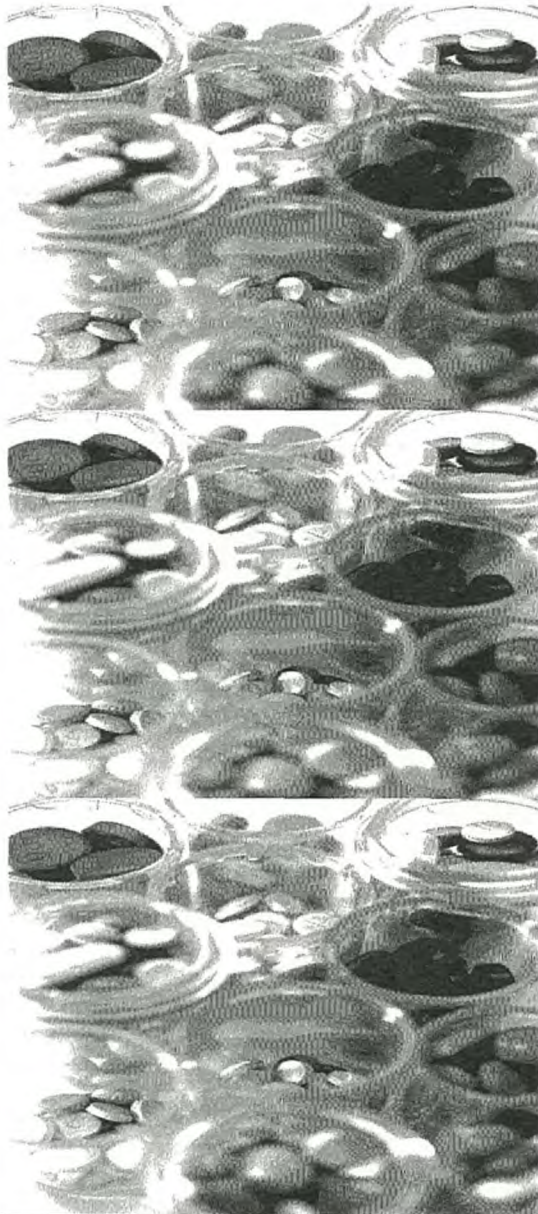
Dimensions:

**2 and 6/16" tall with cap, 2 and 3/16" tall w/o cap.
1 and 7/16" diameter, 13/16" mouth.**

<http://cgi.ebay.com/ws/eBayISAPI.dll?ViewItem&item=280580022565&si=D4v3gSX0l...> 10/28/2010

Fentanyl Transmucosal Product Tampering





Comments, Feedback, Questions

Thank you for your time